ALLEGED VIOLATION: On or about July 19, 22, 25, and 26, 1946, while the drugs were being held for sale after shipment in interstate commerce, the defendant removed portions of the drugs from the bottles and boxes in which they had been shipped, repacked them in boxes, and sold them to various persons without a prescription, which acts of the defendant resulted in the drugs being misbranded. The repackaged *sulfathiazole tablets* were labeled "Sulfathiazole"; the repackaged *thyroid tablets* were labeled in part "1 before meal twice daily Ellis Drug Store"; the repackaged *seconal pulvules* were labeled in part "(1) at Bed time Ellis Drug Store"; and the repackaged *nembutal capsules* were labeled in part "Nembutal 1 Evening upon retiring."

NATURE OF CHARGE: Misbranding, Section 502 (d), the *seconal pulvules* and the *nembutal capsules* were drugs for use by man and contained a chemical derivative of barbituric acid, which derivative had been found, by the Administrator of the Federal Security Agency, after investigation, to be and by regulations designated as habit-forming, and the labels of the repackaged drugs failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith, the statement "Warning – May be habit-forming."

Misbranding, Section 502 (e) (2), the *thyroid tablets* were fabricated from 2 or more ingredients, and the label of the repackaged tablets failed to bear the common or usual name of each active ingredient, including the name and quantity or proportion of thyroid contained therein.

Misbranding, Section 502 (f) (1), the labeling of the *sulfathiazole tablets* and the *thyroid tablets* and the *nembutal capsules* was inadequate, since the repackaged *sulfathiazole tablets* bore no labeling containing directions for use, and since the directions "1 before meals twice daily" and "1 Evening upon retiring" on the boxes of the *thyroid tablets* and the *nembutal capsules*, respectively, were not adequate directions for use.

Misbranding, Section 502 (f) (2), the repackaged *sulfathiazole tablets* and the *thyroid tablets* and the *nembutal capsules* bore no labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health and against unsafe dosage and methods and duration of administration.

Misbranding, Section 502 (j), the repackaged *thyroid tablets* were dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling thereof, "1 before meal twice daily."

DISPOSITION: June 4, 1947. A plea of guilty having been entered, the court imposed a fine of $50 on each of the 4 counts of the information.

2252. Misbranding of Brown's Neuritis Capsules. U. S. v. Randal J. Brown (Thomas A. Brown Pharmacy). Plea of nolo contendere. Defendant fined $200 and placed on probation for 1 year. (F. D. C. No. 21435. Sample Nos. 5433–H, 5439–H, 5440–H.)

INFORMATION FILED: December 13, 1946, District of New Jersey, against Randal J. Brown, trading as the Thomas A. Brown Pharmacy, Trenton, N. J.

ALLEGED SHIPMENT: On or about January 24 and February 19 and 20, 1946, from the State of New Jersey into the States of Delaware and Pennsylvania.

PRODUCT: Analyses disclosed that the product was a gelatin capsule containing a mixture of about 5 grains of cinchophen, with acetophenetidin, caffeine, emodin bearing drugs, and other materials.

NATURE OF CHARGE: Misbranding, Section 502 (a), the name of the article *Neuritis Capsules* was false and misleading, since it represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of neuritis, whereas the article would not be efficacious for such purposes; Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents, in that the bottle containing the article bore no label containing a statement of the quantity of the contents; and, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from 2 or more ingredients, and its label failed to bear the common or usual name of each active ingredient.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, in that the article, by reason of the

fact that it contained cinchophen, was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, i. e., "One every 3 hours, follow with glass of water."

DISPOSITION: April 7, 1947. A plea of nolo contendere having been entered, the court imposed a fine of $200 on count 3 of the information. With respect to counts 1 and 2 of the information, the court suspended the imposition of sentence and placed the defendant on probation for 1 year, conditioned that he do nothing in conflict with the Federal Food, Drug, and Cosmetic Act, and that he stop the use of cinchophen, unless it appears in a prescription of a duly authorized physician.

2253. Misbranding of devices known as Anatatherm. U. S. v. 5 Devices * * *. (F. D. C. No. 23194. Sample No. 22246–H.)

LIBEL FILED: June 17, 1947, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about May 31, 1946, by the Miller Electro Research Laboratories, from Milwaukee, Wis.

PRODUCT: 5 devices known as *Anatatherm* at St. Louis, Mo., together with 12 circulars entitled "How the Anatatherm SW 150 Short Wave internal heat treatment relieves, corrects, stimulates" and 6 circulars entitled "The New Anatatherm Short Wave Internal Heat Treatment for Health." Examination showed that *Anatatherm* was a device to apply short radio waves to the body.

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used with the frequency or duration prescribed, recommended, and suggested in its labeling, i. e., "Treatment Duration: Apply average power of Anatatherm for a period not to exceed one half hour. Three to four treatments per day are generally permissible."

Further misbranding, Section 502 (a), certain statements on the direction cards packed with the article and in the above-mentioned circulars accompanying the article were false and misleading. These statements represented and suggested that the article may be safely and efficaciously used in the treatment of impaired health, sluggish bowels, biliousness, gas pains, intestinal flu, colitis, painful hemorrhoids, prostatitis, colds, painful breathing, catarrhal congestion, asthmatic conditions, localized inflammation, neuralgia myalgia, chronic localized arthritis, arthritis deformans, tired, aching joints, neuritis, sluggish kidneys, grippe, contusions, muscle strains, myositis ossificans, sprains and dislocations, traumatic tenosynovitis, chronic arthritis, myositis and myofascitis (lumbago), fractures, genito-urinary conditions, pelvic infections, respiratory diseases, gastrointestinal diseases, acute and chronic sinusitis, diabetes, paralysis, abscesses, articular rheumatism, asthma, backache, bladder disorders, blood clot, boils, Bright's disease, bronchitis, bursitis, catarrh, carbuncle, colic, congestion, constipation, convulsions, cough, cystitis, deafness, discharge, dropsy, ear disorders, felon, fever, fistula, fracture, furuncles, gall bladder inflammation, gas pressure, headaches, hepatic disorders, hemorrhoids, indigestion, influenza, jaundice, kidney inflammation, laryngitis, lesions, lumbago, mastoiditis, muscular tension, nausea, nephritis, osteitis, ovaritis, peritonitis, pharyngitis, phlebitis, pleurisy, pneumonia, quinsy, rheumatism, salpingitis, sciatica, silicosis, stiff neck, synovitis, teeth abscess, thrombosis, tonsillitis, tooth extractions, ulcers, and whooping cough. The article may not be safely used and was not efficacious in the treatment of such diseases, conditions, and symptoms.

DISPOSITION: December 3, 1947. The Miller Electro Research Laboratories, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2254. Misbranding of sulfathiazole tablets. U. S. v. Jordan James Sullivan (Sullivan's Pharmacy). Tried to the court. Judgment for the Government. Defendant fined $200 and placed on two years' probation. Appealed to the Circuit Court of Appeals; judgment of District Court reversed. Certiorari to Supreme Court; judgment of District Court affirmed. (F. D. C. No. 16600. Sample Nos. 64091–F, 64236–F.)

INFORMATION FILED: January 2, 1946, Middle District of Georgia, against Jordan James Sullivan, trading as Sullivan's Pharmacy, at Columbus, Ga.

*See also Nos. 2251, 2255.